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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,547

10/29/2003

Shu-Ping Yang

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21186

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03/19/2007

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EXAMINER

SOROUGH, ALI

ART UNIT

PAPER NUMBER

1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/696,547	Applicant(s) YANG ET AL.	
	Examiner Ali Soroush	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication;
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10, 13-23, 26, 29, 30-33, 36-38, 41, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldacci (EP 0769298 A2, Published 04/23/1997).

Baldacci teaches, "The present invention relates to the topical use of hyaluronic acid and Doderleins bacillus in the prevention and treatment of vaginal diseases caused by harmful agents, by a reduced oestrogen supply and/or by a changed equilibrium of the vaginal bacterial flora." (See abstract). "After menopause, the low level of glycogen in the vaginal mucosa is the main cause of senile vaginitis, the severity of which is partly attenuated by the state of atrophy of the vagina." (See page 2, Lines 35-36). The thinning of vaginal mucosa, i.e. death of epithelial cells, characterizes the atrophy of the vagina. "Biochemical study of the cervico-vaginal tissue demonstrates the role played by hyaluronic acid and by other glycosaminoglycans in the formation and function of the vaginal mucus which, as is known, owing to its physical properties, such as adhesiveness, viscosity and gel formation, exhibits a general anti-bacterial activity." (See page 2, Lines 53-56). "It is clear from the above considerations that both Doderlein's bacillus and hyaluronic acid principally and particularly have a restorative

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function ..." (See page 3, Lines 1-2). "Hyaluronic acid acts by restoring the vaginal mucus content and by repairing the tissue damage ..." (See page 3, Line 19). "The present invention relates to the topical use of hyaluronic acid and Doderlein's bacillus in the treatment of the states of ... dystrophy and atrophy owing to the lack of oestrogen hormone and senile vaginitis." (See page 3, Lines 6-11). Baldacci further teaches, "The topical application may involve globi, pessaries, creams, ointments, lotions, salves and other types of application formulation for topical use in the vagina containing the two active ingredients in the following dosages: hyaluronic acid: from 2 to 50 mg per unit dose ..." (See page 3, Lines 13-16). "The present invention were the subject of preliminary pharmacological tests using the two active ingredients and a mixture thereof both in lyophilized form and in the form of a pessary containing the customary excipients and carriers." (See page 3, Lines 33-35). In regards to the increased production of glycogen by the vaginal epithelial cells is an inherent characteristic of hyaluronic acid in the composition and vaginal insert. The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the

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discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." For the foregoing reasons the instantly claimed invention is anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldacci (EP 0769298 A2, Published 04/23/1997) in view of Somberg et al. (Clinical Therapeutic Conference, Journal of Clinical Pharmacology (32), Pages 774-778, Published 1992).

Applicant Claims

Applicant claims a method of treating a vaginal condition in a mammal comprising administering to a mammal an effective amount of a composition comprising a hyaluronic acid that increases epithelial cell growth and production of glycogen.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Baldacci have been set forth above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)***

Baldacci lacks a teaching of increased glycogen production due to the administration of the treating composition. Somberg et al. cure this deficiency.

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

Somberg et al. teaches, "Decreased glycogen within the vaginal epithelium causes thinning of the vaginal mucosa, atrophic vaginitis ..." (See page 774, Column 1, Lines 24-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Baldacci and Somberg et al. One would have been motivated to do this because one of the conditions of atrophic vaginitis is reduction of glycogen and therefore it would have been obvious that hyaluronic acid would increase the amount of glycogen since it acts as restorative compound on this condition, as taught by Baldacci. For the foregoing reasons the instantly claimed invention is made obvious.

2. Claims 8, 9, 11, 12, 24, 25, 27, 28, 39, 40, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldacci (EP 0769298 A2, Published 04/23/1997) in view of Rhee et al. (EP 0656215 A1, Published 11/01/1994).

Applicant Claims

Applicant claims a composition / vaginal insert that comprises a hyaluronic acid and a carrier wherein the hyaluronic acid is mixed or covalently linked to a non-polysaccharide polymer. Applicant further claims a method of treating vaginal condition with said composition.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Baldacci have been set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Baldacci lacks a teaching of the hyaluronic acid being covalently linked to a non-polysaccharide polymer. This deficiency is cured by the teachings of Rhee et al.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Rhee et al. teaches, "The invention relates to the biocompatible conjugates which can be used in a variety of medical and pharmaceutical applications." (See page 4, Lines 19-20). "Biocompatible, pharmaceutically acceptable, nonimmunogenic conjugates are formed by covalently binding glycosaminoglycans, and/or derivatives thereof, to a synthetic hydrophilic polymer, such as an activated polyethylene glycol ..."

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(See page 4, Lines 6-8). "The term 'glycosaminoglycan' is intended to encompass complex polyssacharides which are not biologically active ... having repeating units of either the same saccharide subunit or two different saccharide subunits. Some examples of glycosaminoglycans include dermatan sulfate, hyaluronic acid ..." (See Page 5, Lines 49-52). "Hydrophilic synthetic polymers used herein include activated forms of polyethylene glycol (PEG), polyoxyethylene, polymethylene glycol, polytrimethylene glycols, polyvinylpyrrolidones, and derviates thereof with activated PEG being particularly preferred." (See page 10, Lines 51-53). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Baldacci and Rhee et al. One would have been motivated to do this because conjugating a polymer to the hyularonic acid gives several advantages: 1. Greater degree of stability; 2. Superior handling characteristics; 3. Decreased immune reaction; and 4. Improved moldability, malleability, and elasticity. (Seepage 5, Lines 1-13). For the foregoing reasons the instantly claimed invention is made obvious.

Conclusion

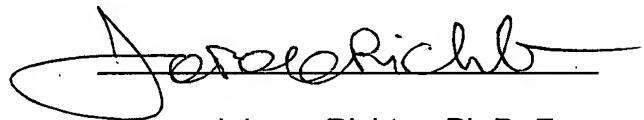
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
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A handwritten signature in black ink, appearing to read 'Johann Richter', with a large, stylized loop at the beginning and a horizontal line extending to the right.

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600